

DETAILED ACTION

Election/Restrictions

Applicant's election of the species, Pentaerythritol-tetrakis-(3-mercaptopropionate) ("QT") and Poly(ethylene glycol) diacrylate ("PEGDA") in the reply filed on July 14, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-25 have been examined to the extent they read on the elected species.

The instant claims are directed to a method of sterilization by applying in situ two components and forming polymer within the tissue and thereby achieve sterilization.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,103,254 ('254), US 5,989,580 ('580) and Abdala et al., J. Vasc. Interv. Radiol., 2001;12(8):979-984 (abstract) in view of Vernon et al., J. Biomed. Mater. Res., 2002;62:1-10 (from the IDS filed February 28, 2007) and Hakverdi et al., Advance in Contraception, 1994;10:51-56.

By using occluding agents to block the fallopian tube (female) and vas deferens (male) is a well-known method of sterilization. For example '254 teaches a method of sterilization by delivering biocompatible polymer to vas deferens in male subject (See the abstract for example). '580 teaches a method of sterilization by delivering biocompatible polymer and a radiopaque agent such as barium sulfate to fallopian tube in female subject (see abstract and claims 1 and 19). Also Abdala et al. teaches the effectiveness of ethylene vinyl alcohol copolymer was delivered to the fallopian tube in a rabbit model for sterilization (see the abstract).

The primary references do not expressly teach QT and PEGDA. The primary references do not expressly teach the use of a buffer and surfactant. The primary references do not expressly teach the use of progesterone in the method of sterilization.

Vernon et al. teaches the use of QT and PEGDA to form a polymer in situ that can be useful as bone cement (See page 1, col. 2). Vernon et al. also teaches the use of buffering agent (PBS) in preparing dispersion of the agents (see page 3, col. 1) and the emulsion type using PEP (polyethylene glycol-co-polypropylene glycol) (a surfactant herein claimed) (see page 4, col. 1).

Hakverdi et al. teaches one of the side effects of tube occlusion sterilization as significant decrease in progesterone level (see the abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ QT, PEGDA, a buffering agent, and a surfactant in the method of tube occlusion for sterilization. It would have been obvious to one of ordinary

skill in the art at the time the invention was made to employ progesterone in the method of sterilization.

One of ordinary skill in the art would have been motivated to employ QT, PEGDA, a buffering agent, and a surfactant in the method of tube occlusion for sterilization since QT and PEGDA are known that can form a biocompatible polymer and buffering agent and surfactant are well-known to be used in solution delivering QT and PEGDA to the site. Employing the resulting polymer in the method of sterilization disclosed in the primary references would therefore been reasonably expected to be effective for sterilizing female and male subject alike.

One of ordinary skill in the art would have been motivated to incorporate progesterone in the method of sterilization since decreased progesterone level is observed after tube occlusion method of sterilization. Therefore, one of ordinary skill in the art would have been motivated to supplement progesterone in patient receiving such method of sterilization and thereby avoid the reduction of progesterone level in the such patients. The examiner notes that the timing of the crosslinking reaction between QT and PEGDA as recited in claims 16-17 are considered as their intrinsic properties of QT and PEGDA.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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